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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/696,727

10/28/2003

Rush E. Simonson

025929-000200US

6338

20350 7590 07/09/2008
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EXAMINER

ARAJ, MICHAEL J

ART UNIT

PAPER NUMBER

3733

MAIL DATE

DELIVERY MODE

07/09/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/696,727	Applicant(s) SIMONSON, RUSH E.	
	Examiner MICHAEL J. ARAJ	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21-23 and 25-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michelson (U.S. Patent No. 6,436,098) in view of Ralph et al. (U.S. Patent No. 5,989,291).

Michelson discloses a surgical method for replacing damaged fibrocartilage between facing superior and inferior vertebrae in a patient's spine, each having a spinous process, comprising the steps of making a posterior incision into a patient's back in the vicinity of said damaged fibrocartilage, through said posterior incision, removing damaged fibrocartilage between said superior and inferior vertebrae, creating channels (as seen from Fig. 11A) in said facing superior and inferior vertebral surfaces and inserting posteriorly at least two permanently articulating vertebral implant devices between said superior and inferior vertebrae wherein there is at least one of said articulating vertebral devices on each side of a vertical medial plane defined by the spinous processes of said superior and inferior vertebrae. The channels formed are approximately parallel to the said vertical medial plane defined by said spinous processes of said superior and inferior vertebrae. The articulating devices each

comprise a cushioning member (122) sandwiched between a superior (100) and an inferior support (106) wherein said superior support is placed into fixed contact with said superior vertebrae and said inferior support is placed into fixed contact with said inferior vertebrae. The cushioning member can be considered to be a dampening matrix since it dampens part of the load absorbed. Also, protrusions (114) are formed into one or more of said supports which penetrate into vertebral tissue.

Michelson discloses the claimed invention except for two permanently articulated vertebral implants that permanently allow continued movement of said vertebrae with respect to one another or attaching two sets of supports to each of said superior and inferior vertebrae. Ralph et al. disclose an articulating implant device (Fig. 6) that allows for permanent movement. The internal portion of the device (130) also acts as a spring that provides as strong restoring force when a compressive load is applied to walls of the device. Ralph et al. also disclose attaching two sets of supports (100a, 100b) to each of said superior and inferior vertebrae. It would have been obvious to one skilled in the art at the time the invention was made to have created the method of Michelson with two articulating members with supports in view of Ralph, in order to have a method that leaves the patient with some mobility in the vertebra.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Michelson (U.S. Patent No. 6,436,098) in view of Ralph et al. (U.S. Patent No. 5,989,291) in further view of Beer et al. (U.S. Patent No. 5,458,642).

The combination of Michelson and Ralph et al. discloses the claimed invention except for the dampening matrix including a hydrogel core. Beer et al. disclose the use

of a dampening matrix using a hydrogel core. It would have been obvious to one skilled in the art at the time the invention was made to the combination of Michelson and Ralph et al. to have the cushioning member include a hydrogel core in view of Beer et al. because the coil spring distributes forces acting on the disc between the springs and the hydrogel core to allow for normal movement of the vertebrae.

Response to Arguments

Applicant's arguments filed April 9, 2008 have been fully considered but they are not persuasive. Applicant argues that Michelson invention teaches away from their invention. Michelson does not teach the use of permanently articulating members that allows continued movement, but where Michelson is lacking is where Ralph teaches this void. Ralph does disclose the use of these articulating members to maintain some mobility in the spine. Where Michelson is lacking Ralph teaches and vice versa.

Applicant also argues that the Ralph implant is not suitable posterior insertion because it is wedge shaped with one end being narrower than the other. If one were to implant the device as suggested by the applicant then it is true that kyphosis would occur, but because of the spring-like characteristic of Ralph this condition can be avoided. Upon placement of the device implant can be compressed and then implanted to allow it to fit into the disk space. This would allow the implant to be put in posteriorly and avoid kyphosis.

Additionally applicant argues that Beer disclose a single articulating vertebral implant device and there is no teaching to suggest two devices. The Beer reference is

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used for its teaching of the hydrogel core and not the use of two such devices of Beer. Michelson and Ralph has adequate teaching of two implants. Additionally, one could have applied the duplication of parts, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL J. ARAJ whose telephone number is (571)272-5963. The examiner can normally be reached on M-F 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael J Araj/
Examiner, Art Unit 3733

/DAVID J ISABELLA/
Supervisory Patent Examiner, Art Unit 3774